

IN THE UNITED STATES PATENT AND TRADEMARKS OFFICE

In re Application of: Cagle et al.

Serial No: NYA  
(Continuation Serial No. 10/200,868)

Confirmation No: NYA  
(Continuation Confirmation No. 5897)

Filed: November 17, 2003

Examiner: NYA  
(Continuation Application: Zohreh Fay)

Group Art Unit: NYA  
(Continuation Application: 1614)

For: ANTIBIOTIC COMPOSITIONS FOR THE TREATMENT OF THE EYE, EAR  
AND NOSE

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.56 AND §1.97(b)(1)**

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56, Applicants direct the attention of the Examiner to the sixty-six (66) references listed on the attached Form PTO-1449 (Sheets 1-6).

Applicants are submitting copies foreign patent documents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with sufficient postage to the United States Postal Service as Express Mail EV 124 463 558 US, addressed to: Mail Stop Patent Applications, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date:

Date: November 17, 2003

Name: Deborah Weinschenk

Signature: 

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Filed: November 17, 2003  
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Applicants request that the listed references be considered during prosecution of this application and made of record herein.

Respectfully submitted,  
ALCON RESEARCH, LTD.

Date November 17, 2003

By   
Gregg C. Brown  
Reg. No. 30,613

Enclosures: Form PTO-1449 (6 pages)  
Foreign Patent Documents & Non-Patent Literature (35 references)

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Docket No. 1732 US F2

FORM PTO-1449 U.S. DEPT. OF COMMERCE Patent & Trademark Office		ATTY. DOCKET NO. 1732 US F2	SERIAL NO. NYA				
LIST OF DOCUMENTS CITED BY APPLICANT  (Use several sheets if necessary)		APPLICANT Cagle et al.					
		FILING DATE November 17, 2003	GROUP NYA				
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/ZF/	AB1	4,474,751	10/02/84	Haslam et al.			
	AB1	4,551,456	11/05/85	Katz			
	AC1	4,670,444	06/02/87	Grohe et al.			
	AB1	4,710,495	12/01/87	Bodor			
	AE1	4,730,013	03/08/88	Bondi et al.			
	AF1	4,844,902	07/04/89	Grohe			
	AC1	4,920,120	04/24/90	Domagala et al.			
	AH1	4,980,470	12/25/90	Masuzawa et al.			
	AI1	4,990,517	02/05/91	Petersen, et al.			
	AJ1	4,996,335	02/26/91	Bodor			
	AK1	5,059,597	10/22/91	Petersen et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES      NO
/ZF/	AE1	CA 2,086,914	07/11/93	Canada			X
	AM1	EP 0 982 031	03/01/00	Europe			X
	AN1	ES S/N 08320	04/20/93	Spain			X
	AO1	WO 90/01933	03/08/90	WIPO			X
	AP1	WO 96/39146	12/12/96	WIPO			X
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
/ZF/	AR1	Blondeau, Joseph M., "A review of the comparative in-vitro activities of 12 antimicrobial agents, with focus on five new 'respiratory quinolones', <i>Journal of Antimicrobial Chemotherapy</i> , vol. 43, Suppl. B, pages 1-11 (1999)					
/ZF/	AS1	Elies, W., "Newer fluoroquinolones in the treatment of ENT infections", <i>Chemotherapie Journal</i> , 7/3, pages 93-97 (1998) (no translation), <i>XP000892813</i>					
/ZF/	AT1	Ernst et al., "Levofloxacin and trovafloxacin: The next generation of fluoroquinolones?", <i>Clinical Review</i> , <i>Am. J. Health-Syst. Pharm.</i> , vol. 54, pages 2569-2584 (114/19/97)					

EXAMINER	/Zohreh Fay/ (09/16/2009)	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
/ZF/	AA2	5,149,694	09/22/92	Cagle et al.			
	AB2	5,164,402	11/17/92	Brighty			
	AC2	5,185,337	02/09/93	Fujii, deceased et al.			
	AD2	5,223,493	06/29/93	Boltralik			
	AL2	5,416,096	05/16/95	Petersen et al.			
	AF2	5,480,879	01/02/96	Petersen et al.			
	AG2	5,520,920	05/28/96	Castillo, et al.			
	AH2	5,540,930	07/30/96	Guy et al.			
	AI2	5,563,138	10/08/96	Ueda et al.			
	AJ2	5,597,560	01/28/97	Bergamini et al.			
	AK2	5,607,942	03/04/97	Petersen et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
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/ZF/	AL2	WO 98/06435	02/19/98	WIPO			X
	AM2	WO 99/15172	04/01/99	WIPO			X
	AN2	WO 00/18385	04/06/00	WIPO			X
	AO2	WO 00/18385	04/06/00	WIPO			X
	AP2	WO 00/18388	04/06/00	WIPO			X
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
/ZF/	AR2	Gootz et al., "Fluoroquinolone antibiotics: SAR mechanism of action, resistance, and clinical aspects", Medicinal Research Reviews, vol. 16, pages 433-486 (1996)					
/ZF/	AS2	Kaw et al., "The penetration of trovafloxacin into the eye and CSF of rabbits", IOVS, vol. 40, no. 4, page S88 (03/15/1999); XP-000892619					
/ZF/	AT2	Kraserman et al., "Efficacy of Moxifloxacin against Staphylococcus aureus in respiratory tract and skin and skin structure infections", Journal Of Antimicrobial Chemotherapy, vol. 44, no. Suppl. A, pp 150 (7/99); XP000892776					

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/ZF/	AA3	5,631,004	05/20/97	Cagle et al.			
	AB3	5,665,373	09/09/97	Robertson et al.			
	AC3	5,679,665	10/21/97	Bergamini et al.			
	AB3	5,849,752	12/15/98	Grunenberg et al.			
	AE3	5,854,241	12/29/98	Hallenbach et al.			
	AB3	5,912,255	06/15/99	Bussell			
	AC3	6,093,417	07/25/00	Petrus			
	AH3	6,440,964	08/27/02	Cagle, et al.			
	AI3	6,509,327	01/21/03	Cagle, et al.			
	AJ3						
↓	AK3						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES      NO
/ZF/	AL3	WO 00/18404	04/06/00	WIPO			X
	AM3	EP 1 025 846	08/90/00	Europe			X
	AB3	WO 01/45679	06/28/01	WIPO			X
↓	AO3	WO 01/89495	11/29/01	WIPO			X
	AE3						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
/ZF/	AR3	McLeod et al., "The effect of topical trovafloxacin in a rabbit streptococcus pneumoniae keratitis model", IOVS vol. 40, no. 4, page S689 (03/15/1999) XP-000892625					
/ZF/	AS3	NCCLS Document M7-A4, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically", 4th Edition					
/ZF/	AT3	"New Antimicrobial Agents Approved by the U.S. Food and Drug Administration in 1997 and New Indications for Previously Approved Agents" Antimicrobial Agents and Chemotherapy, vol. 42, no. 4, pages 987-988 (4/1998); XP000872060					

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	AA4						
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	AC4						
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	AE4						
	AF4						
	AC4						
	AH4						
	AI4						
	AJ4						
	AK4						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES
							NO
	AE4						
	AM4						
	AN4						
	AD4						
	AE4						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
/ZF/	AR4	NG et al., "Treatment of experimental staphylococcus epidermidis endophthalmitis with oral trovafloxacin" <i>American Journal of Ophthalmology</i> , vol. 216 (2), pages 278-287 (08/1998)					
/ZF/	AS4	Patent Abstracts of Japan, vol. 1998, no. 10 (08/31/1998), JP 10 130148 05/19/1998 abstract					
/ZF/	AT4	Patent Abstracts of Japan, vol. 012, no. 472 (12/09/1988), JP 63 190826 08/08/1988 abstract					

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		AES					
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		AG5					
		AHS					
		AIS					
		AJS					
		AK5					
FOREIGN PATENT DOCUMENTS							
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							YES      NO
		AES					
		AM5					
		AES					
		AES					
		AP5					
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
/ZF/	ARS	Pediatric Research, 104th Annual Meeting of the American Pediatric Society and the 63rd Annual meeting of the Society for Pediatric Research, vol. 35, no. 4, Part 2, page 191A, Seattle, Washington (05/02-05/94)					
/ZF/	ASS	Senturia, Ben, "Etiology Of External Otitis", <u>Laryngoscope</u> , volume 55, pages 277-293 (1945)					
/ZF/	AT5	Tillotson, G. S., "Quinolones: structure-activity relationships and future predictions", <u>J. of Medical Microbiology</u> , vol. 44, pages 320-324 (1996)					

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AB6							
AB6							
AE6							
AB6							
AE6							
AB6							
AG6							
AH6							
FOREIGN PATENT DOCUMENTS							
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						YES	NO
A16							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
AJ6	Vincent et al., "Pharmacokinetics and safety of trovafloxacin in healthy male volunteers following administration of single intravenous doses of the prodrug, atrafloxacin", <u>Journal of Antimicrobial Chemotherapy</u> , vol. 39, Suppl. B, pages 75-80 (01/01/1997)						
AK6	Weiss, Lee R., "Therapeutic Pathways for Antimicrobial Use: General Overview", <u>The American Journal of Managed Care</u> , vol. 4, no. 10, Sup., pages S543-S549 (1988)						
AL6	Wentland, Mark P., "Structure-activity relationships of fluoroquinolones", <u>The New Generation of Quinolones</u> , (Siporin, C., Heifetz, C. L. & Domagala, J. M., Eds), pages 1-43, Marcel Dekker, New York (1990)						
AM6	Goldstein, et al., "In Vitro Activity of Bay 12-8039, a New 8-Methoxyquinolone, Compared to the Activities of 11 Other Oral Antimicrobial Agents Against 390 Aerobic and Anaerobic Bacteria Isolated from Human and Animal Bite Wound Skin and Soft Tissue Infections in Humans", <u>Antimicrobial Agents and Chemotherapy</u> , July 1997, pages 1552-1557						
AN6	Goldstein, et al., "Comparative In Vitro Activities of Azithromycin, Bay y 3118, Levofloxacin, Sparfloxacin, and 11 Other Orgal Antimicrobial Agents Against 194 Aerobic and Anerobic Bite Wound Isolates", <u>Antimicrobial Agents and Chemotherapy</u> , May 1995, pages 1097-1100						
AO6	Rubinstein, "Pharmacology - Tissue Distribution", <u>International Moxifloxacin Symposium, 1<sup>st</sup> (2000)</u> Meeting date 1999, pages 130-133; Editors: Mandell, Lionel						

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